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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,795	01/13/2004	Samuel D. Prien	13241US03	1541
23446 7590 12/12/2007 MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/756,795

Applicant(s)

PRIEN, SAMUEL D.

Examiner

William H. Beisner

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polyak et al.(US 2002/0115634) in view of Rath et al.(US 5,230,996).

The reference of Polyak et al. discloses a perfusion fluid that includes a free radical scavenger in an amount effective to increase the length of the period which an ex vivo organ will remain viable in the perfusion fluid (See paragraph [0016]).

While the reference of Polyak et al. discloses a preservation solution that includes an oxygen radical scavenger, claim 6 differs by reciting that the composition is provided in time-release form.

The reference of Rath et al. discloses that when exposing a tissue to a desired treatment composition, it is known in the art to provide the treatment composition in time-release form to achieve constant fluid concentrations of the composition over time (See column 6, lines 23-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the scavenger of the primary reference in time-release form for the known and expected benefit suggested by the reference of Rath et al.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polyak et al.(US 2002/0115634) in view of Rath et al.(US 5,230,996) taken further in view of Chien et al.(US 3,992,518).

The combination of the references of Polyak et al. and Rath et al. has been discussed above.

Claim 7 differs by reciting that the time-release composition includes a body of organosiloxane material.

The reference of Chien et al. discloses that the use of organosiloxane material is conventional in the art as a time-release carrier material (See Example 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an organosiloxane material as a carrier for the composition of the modified primary reference for the known and

expected result of providing an art recognized means for providing the time-release feature suggested by the reference of Rath et al.

5. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKIO (JP 06-305901) in view of Rath et al. (US 5,230,996).

The reference of AKIO discloses an apparatus (See Figure 1) that includes a perfusion loop that includes an organ container (9), a bubble remover (8) and an oxygenator (6). With respect to the claimed free radical scavenger, the reference discloses that the perfusion media includes adenosine (See the English language Abstract and paragraph [0021] of the English language machine translation).

While the reference of AKIO discloses a preservation solution that includes adenosine, claims 1, 2 and 6 differ by reciting that the composition is provided in time-release form.

The reference of Rath et al. discloses that when exposing a tissue to a desired treatment composition, it is known in the art to provide the treatment composition in time-release form to achieve constant fluid concentrations of the composition over time (See column 6, lines 23-27).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the scavenger of the primary reference in time-release form for the known and expected benefit suggested by the reference of Rath et al.

With respect to the perfusion fluid of claim 5, the reference discloses that the perfusion media includes adenosine (See the English language Abstract and paragraph [0021] of the English language machine translation.

6. Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKIO (JP 06-305901) in view of Rath et al.(US 5,230,996) taken further in view of Chien et al.(US 3,992,518).

The combination of the references of AKIO (JP 06-305901) and Rath et al. has been discussed above.

Claims 3 and 7 differ by reciting that the time-release composition includes a body of organosiloxane material.

The reference of Chien et al. discloses that the use of organosiloxane material is conventional in the art as a time-release carrier material (See Example 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an organosiloxane material as a carrier for the composition of the modified primary reference for the known and expected result of providing an art recognized means for providing the time-release feature suggested by the reference of Rath et al.

Response to Arguments

7. With respect to the rejection of Claims 1, 4 and 5 under 35 U.S.C. 102(b) as being anticipated by AKIO (JP 06-305901), this rejection has been withdrawn in view of Applicant's amendments and related comments filed 9/28/2007 (See page 4 of Applicant's response filed 9/28/2007).

8. With respect to the rejection of Claim 4 under 35 U.S.C. 102(b) as being anticipated by Polyak et al.(US 2002/0115634), this rejection has been withdrawn in view of Applicant's amendments and related comments filed 9/28/2007 (See page 4 of Applicant's response filed 9/28/2007).

9. With respect to the rejection of Claim 6 under 35 U.S.C. 103(a) as being unpatentable over Polyak et al.(US 2002/0115634) in view of Rath et al.(US 5,230,996), Applicant argues that the rejection is improper for the following reasons (See pages 4-5 of Applicant's response filed 9/28/2007):

i) *The reference of Polyak et al. discloses "solutions" rather than a "time-release composition" required of claim 6.*

ii) *The reference of Rath et al. does not disclose "a free radical scavenger" which is required of claim 6.*

iii) *The combination of the references of Polyak et al. and Rath et al. is not obvious because the rejection lacks a reason why one of ordinary skill in the art would provide the free radical scavenger solution of Polyak et al. into time release form.*

Applicant stresses that the reference of Rath et al. is not pertinent to the problems addressed when maintaining an ex vivo organ.

In response to comments i) and ii) above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, as stated in the rejection of record, it is the combination of the references that render the instant claims obvious. Had a single reference met all of the claim limitations, the claims would have been rejected under 35 USC 102 rather than under 35 USC 103.

In response to comment iii) above, as indicated by the Supreme Court, any alleged risk of hindsight bias should not be overemphasized so as to defy common sense. See *KSR International Co. v. Teleflex Inc.*, 550 U.S.----, 82 USPQ2d 1385, 1397 (2007). Furthermore, the *KSR* decision makes clear that the teaching, suggestion, or motivation (TSM) test is not the only rationale that may be relied upon to support a conclusion of obviousness. Nevertheless, in this case, the claims can be rejected for obviousness based on the TSM rationale as explained below. In this case, the reference of Polyak et al. discloses a solution used during the storage and/or preservation of an organ or tissue. The solution includes a free radical scavenger. The reference of Rath et al. discloses that when exposing organs or tissues to treatment compositions in solutions during storage, it is known in the art to provide the treatment composition using a time release composition to achieve relatively constant solution

concentrations of the treatment composition over time (See column 6, lines 20-27). In view of this teaching, one of ordinary skill in the art would have been clearly motivated to provide the free radical scavenger of the primary reference of Polyak et al. as a time release composition for the known and predictable result of maintaining a constant concentration of the free radical scavenger in the storage solution over time. The Examiner would also like to point out that the treatment composition of the reference of Rath et al. can include an antioxidant component (See Table 2).

10. With respect to the rejection of Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Polyak et al.(US 2002/0115634) in view of Rath et al.(US 5,230,996) taken further in view of Chien et al.(US 3,992,518), *Applicant argues that the reference of Chien et al. does not disclose the use of time release technology to distribute an antioxidant or maintain an ex vivo organ and that the reference of Chien et al. fails to make up for the shortcomings of the combination of the references of Polyak et al. and Rath et al.* (See page 5 of Applicant's response filed 9/28/2007).

In response to Applicant's comments above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, as stated in the rejection of record, it is the combination of the references that render the instant claims obvious. The reference of Chien et al. was relied upon to address the additional claim feature of claim 7, the Examiner maintains that the combination

of the references of Polyak et al. and Rath et al. meet the claim features required of claim 6.

11. With respect to the rejection of Claims 2 and 6 under 35 U.S.C. 103(a) as being unpatentable over AKIO (JP 06-305901) in view of Rath et al. (US 5,230,996), Applicant argues that the rejection is improper for the following reasons (See page 6 of Applicant's response filed 9/28/2007):

i) *The reference of Akio et al. discloses adenosine in dissolved form rather than as "time-release composition" required of claim 6.*

ii) *The reference of Rath et al. does not disclose "a free radical scavenger" which is required of claim 6.*

iii) *The combination of the references of Akio and Rath et al. is not obvious because the rejection lacks a reason why one of ordinary skill in the art would provide the free radical scavenger solution of Polyak et al. into time release form. Applicant stresses that the reference of Rath et al. is not pertinent to the problems addressed when maintaining an ex vivo organ.*

In response to comments i) and ii) above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, as stated in the rejection of record, it is the combination of the references that render

the instant claims obvious. Had a single reference met all of the claim limitations, the claims would have been rejected under 35 USC 102 rather than under 35 USC 103.

In response to comment iii) above, as indicated by the Supreme Court, any alleged risk of hindsight bias should not be overemphasized so as to defy common sense. See *KSR International Co. v. Teleflex Inc.*, 550 U.S.----, 82 USPQ2d 1385, 1397 (2007). Furthermore, the *KSR* decision makes clear that the teaching, suggestion, or motivation (TSM) test is not the only rationale that may be relied upon to support a conclusion of obviousness. Nevertheless, in this case, the claims can be rejected for obviousness based on the TSM rationale as explained below. In this case, the reference of Akio discloses a solution used during the storage and/or preservation of an organ or tissue. The solution includes a free radical scavenger or adenosine. The reference of Rath et al. discloses that when exposing organs or tissues to treatment compositions in solutions during storage, it is known in the art to provide the treatment composition using a time release composition to achieve relatively constant solution concentrations of the treatment composition over time (See column 6, lines 20-27). In view of this teaching, one of ordinary skill in the art would have been clearly motivated to provide the free radical scavenger or adenosine of the primary reference of Akio as a time release composition for the known and predictable result of maintaining a constant concentration of the free radical scavenger in the storage solution over time. The Examiner would also like to point

out that the treatment composition of the reference of Rath et al. can include an antioxidant component (See Table 2).

12. With respect to the rejection of Claims 3 and 7 under 35 U.S.C. 103(a) as being unpatentable over AKIO (JP 06-305901) in view of Rath et al.(US 5,230,996) taken further in view of Chien et al.(US 3,992,518), *Applicant argues that the combination of the references is improper for the same reasons as set forth with respect to the combination of the references of Akio and Rath et al. with respect to claims 2 and 6. Applicant stresses that the reference of Chien et al. does not disclose the use of time release technology to distribute an antioxidant or maintain an ex vivo organ and that the reference of Chien et al. fails to make up for the shortcomings of the combination of the references of Akio and Rath et al. (See page 5 of Applicant's response filed 9/28/2007).*

In response to Applicant's comments above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, as stated in the rejection of record, it is the combination of the references that render the instant claims obvious. The reference of Chien et al. was relied upon to address the additional claim features of claims 3 and 7, the Examiner maintains that the

combination of the references of Akio and Rath et al. meet the claim features required of claims 2 and 6.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

WHB